

Cholinesterase Monitoring  
of Pesticide Handlers  
in Agriculture  
Report to the Legislature

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*As required by RCW 49.17.288*

**JANUARY 2005**

## Executive Summary

This report is prepared, as required by RCW 49.17.288, to reflect the first year of implementation of the cholinesterase monitoring rule adopted by the Department of Labor and Industries in late 2003. The history of the rule is described in the “background” section beginning on page 4.

During the 2004 spray season, employers included 580 employees in medical monitoring, which involves a baseline test and at least one periodic test. Of those employees, 97 employees (16.7 percent) received at least one test with a 20 percent or greater depression, requiring an evaluation of pesticide handling practices. Of the same group, 22 employees (3.8 percent) were temporarily removed from exposure because of a more significant depression.

In adopting RCW 49.17.285, the Legislature required employers to submit pesticide handling hours to L&I on each employee who received a periodic test. Although employer compliance with this new requirement was modest, L&I was able to obtain reports for 633 of the 911 tests given during the 2004 season. A more detailed discussion of the 2004 results, including L&I’s analysis of the handling hours information, begins on page 6.

The rule as adopted requires agriculture employers whose employees handle organophosphate or N-methyl carbamate Category 1 or 2 pesticides to keep track of each employees’ hours and to make available both baseline and periodic medical tests to those employees who handle covered pesticides above the threshold in the rule. For the first year, the threshold was established at 50 hours during any consecutive 30-day period. The rule also provides that beginning with February 1, 2005, the threshold will drop to 30 hours during any consecutive 30-day period, indicating that this 2005 threshold can be changed “if the data collected during 2004 clearly demonstrates that the threshold should be either lower or higher than thirty hours.”

Stakeholder recommendations related to the handling hours threshold were not in agreement. Based on the arguments presented and the available information, L&I has concluded that implementing the 30-hour threshold as scheduled will comply with the expectations of the rule as adopted, continue to provide effective protections to workers during 2005 based on the best currently available evidence, and ensure that more complete data for future analyses. However, L&I also believes that the question of the appropriate monitoring threshold has not been resolved, and that it should be revisited next year as additional data accumulates.

Overall, the first year’s experience has been a positive one, although there were a number of issues that require further attention and analysis during the second year, and certain stakeholders have expressed stronger concerns about the 2004 experience. L&I will continue to rely upon the expertise of the Scientific Advisory Committee and the perspectives of the Stakeholder Advisory Committee in implementing the medical monitoring program and in evaluating the rule and its effects.

**CHOLINESTERASE MONITORING IN AGRICULTURE**  
**WAC 296-307-148**  
**WASHINGTON STATE DEPARTMENT OF LABOR AND INDUSTRIES**  
**January 6, 2005**

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## Background

Certain pesticides, known as cholinesterase inhibitors, work by attacking the nervous systems of the insects. Those same pesticides can affect the human nervous system. Cholinesterase (acetyl cholinesterase) is an enzyme that removes the chemical neurotransmitter acetylcholine, from the junctions between nerves cells. By doing so, cholinesterase effectively serves as the nervous system's "off switch" and is essential to the normal function of the nervous system.

Exposure to organophosphate or N-methyl-carbamate pesticides may lower the level of available cholinesterase. Without the normal protective levels of cholinesterase, nerves in the body may be over stimulated to the point of exhaustion, leading to symptoms ranging from blurred vision, diarrhea and tremors to seizures, loss of consciousness and even death.

Monitoring cholinesterase levels in the blood through simple laboratory tests can detect cholinesterase depression prior to the onset of illness, as well as provide information regarding the degree of exposure and the effectiveness of control measures.

In December 2003, the Department of Labor and Industries (L&I) adopted the cholinesterase monitoring rule for agricultural pesticide handlers (WAC 296-307-148 through WAC 296-307-14845).<sup>1</sup> The rule was developed following more than 10 years of effort by advocates of such medical monitoring.

In 1993, after evaluating the feasibility and benefits of cholinesterase monitoring, coupled with the protections then being adopted as part of the pesticide Worker Protection Standard, the Washington State Department of Labor & Industries (L&I) recommended cholinesterase monitoring in agriculture (then WAC 296-307-14520). The recommendation included baseline and periodic red blood cell (RBC) and plasma cholinesterase testing for workers handling organophosphate or N-methyl-carbamate pesticides for 30 or more hours in any 30-day period.

In 1997, L&I was asked to implement mandatory cholinesterase monitoring. L&I declined to do so, based on a consideration of available L&I resources and agency priorities. L&I did not, however, decide that a rule was not warranted. L&I's decision not to pursue rulemaking at the time led to legal action to require L&I to act. In 2002, the Supreme Court of the State of Washington in *Rios*<sup>2</sup> upheld the 1993 decision to adopt a recommendation rather than a rule, but required L&I to initiate rulemaking in response to the 1997 request. The current rule as adopted was the result of the rulemaking initiated by L&I following *Rios*.

Cholinesterase monitoring in agriculture has also received legislative attention. In 2003, the Legislature provided funding to offset the rule's medical costs and the cost of the analysis of the rule. In 2004, the Legislature provided additional funding, including funding to reimburse employers for several other rule-related costs. It also adopted RCW 49.17.285 and 49.17.288, the latter of which requires L&I to make annual reports to the Legislature following the first three years of the rule's implementation. This document is the first of those required reports, including the results of the rule's first year and L&I's "data collection, correlation and analysis," particularly as it relates to the relationship between pesticide handling hours and reported cholinesterase depressions ("depressions" are identified when an individual's effective level of cholinesterase drops below certain levels identified in the rule).

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<sup>1</sup> A copy of the rule is attached for reference as Attachment 1.

<sup>2</sup> *Juan Rios and Juan Farias v. Washington Department of Labor & Industries, et al.*, 145 Wn.2d 483, 39 P.3d 961 (2002).

The rule as adopted requires agriculture employers whose employees handle organophosphate or N-methyl carbamate Category 1 or 2 pesticides to keep track of each employees' hours and to make available both baseline and periodic medical tests to those employees who handle covered pesticides above the threshold in the rule. For the first year, the threshold was established at 50 hours during any consecutive 30-day period. The rule also provides that beginning with February 1, 2005, the threshold will drop to 30 hours during any consecutive 30-day period, indicating that this 2005 threshold can be changed "if the data collected during 2004 clearly demonstrates that the threshold should be either lower or higher than thirty hours."<sup>3</sup>

The rule also instituted two advisory groups to work with the L&I in evaluating the rule. The first of these, the Cholinesterase Stakeholder Advisory Committee, was formed last January to replace the informal stakeholder group that had worked with L&I during rule development. The committee includes representatives of growers, farmworkers, and affected agencies.

In addition, the Cholinesterase Scientific Advisory Committee (SAC) was formed specifically to assist with the analysis of testing data and L&I's evaluation of the rule's implementation. This committee includes individuals recommended by both growers and farmworker representatives, as well as other individuals from within Washington and outside the state, all of whom bring a scientific perspective to the rule's analysis. Two members of the SAC also were asked to serve on the stakeholder group, although issues around scheduling and meeting attendance limited their participation somewhat.

During the rule's first two years, the Public Health Laboratory (PHL) in the Washington State Department of Health (DOH) was designated by L&I as the sole laboratory providing analytical services under the rule. Beginning in 2006, the rule allows (but does not require) L&I to identify and approve other laboratories to provide the necessary analytical services.

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<sup>3</sup> WAC 296-307-14810.

## **Statistical Summary of 2004 Experience**

### **Overview**

During the 2004 spray season, employers sent 2630<sup>4</sup> employees in to obtain baseline tests. Of those, 2050 employees did not receive any periodic monitoring, presumably (at least in most cases) because their exposure levels remained below 50 hours in any one 30-day period.<sup>5</sup>

Of the 580 employees who received at least one periodic test, 97 employees (16.7 percent) received at least one periodic test result with a 20 percent or greater depression, requiring the employer to evaluate pesticide handling practices for possible deficiencies.<sup>6</sup>

Of those same 580 employees, 22 (3.8 percent) were removed from exposure due to a more significant depression (at least 30 percent depression in red blood cell (RBC) cholinesterase or at least 40 percent depression in plasma (serum) cholinesterase).<sup>7</sup>

In adopting RCW 49.17.285, the Legislature required employers to submit pesticide handling hours to L&I on each employee who received a periodic test. Although employer compliance with this new requirement was modest, L&I was able to obtain reports for 633 of the 911 tests given during the 2004 season. With slightly fewer tests available when it did its own analysis, the Scientific Advisory Committee (SAC) drew no conclusions based on this data. The SAC also expressed concern that responses received would not be representative of the entire population. L&I believes, however, that the available data provides useful information, provided its limitations are acknowledged and understood.<sup>8</sup>

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<sup>4</sup> This number (2630) includes tests for covered pesticide handlers. Other tests, such as L&I QC testing, tests submitted to the program in error, and the tests submitted by the Washington Farm Bureau, are not included.

<sup>5</sup> In its December 2003 cost analysis as part of the rulemaking, L&I had extrapolated from employer survey data to estimate that there were 1461 employees who would be covered by the monitoring requirements during 2004; given this estimate, and on the much lower number of participants in periodic tests, it seems clear that the number of baselines during 2004 was considerably higher than required. Based on the limited enforcement activity in which L&I engaged during 2004, there is no inspection evidence that a significant number of growers sent employees in for baselines but then failed to follow through with required monitoring (based on the limited information available, it is more likely that at this time unknown number of growers failed to participate at all). However, there is some evidence that employers failed to accurately report hours among at least some handlers who did receive periodic monitoring; it is likely, therefore, that at least some of the employees who received baselines but did not receive periodic tests should have received such periodic monitoring under the rule.

<sup>6</sup> The data reflects a total of 911 periodic tests given to 580 employees. Of those tests, 176 tests (19.3%) identified depression to the work practice evaluation level.

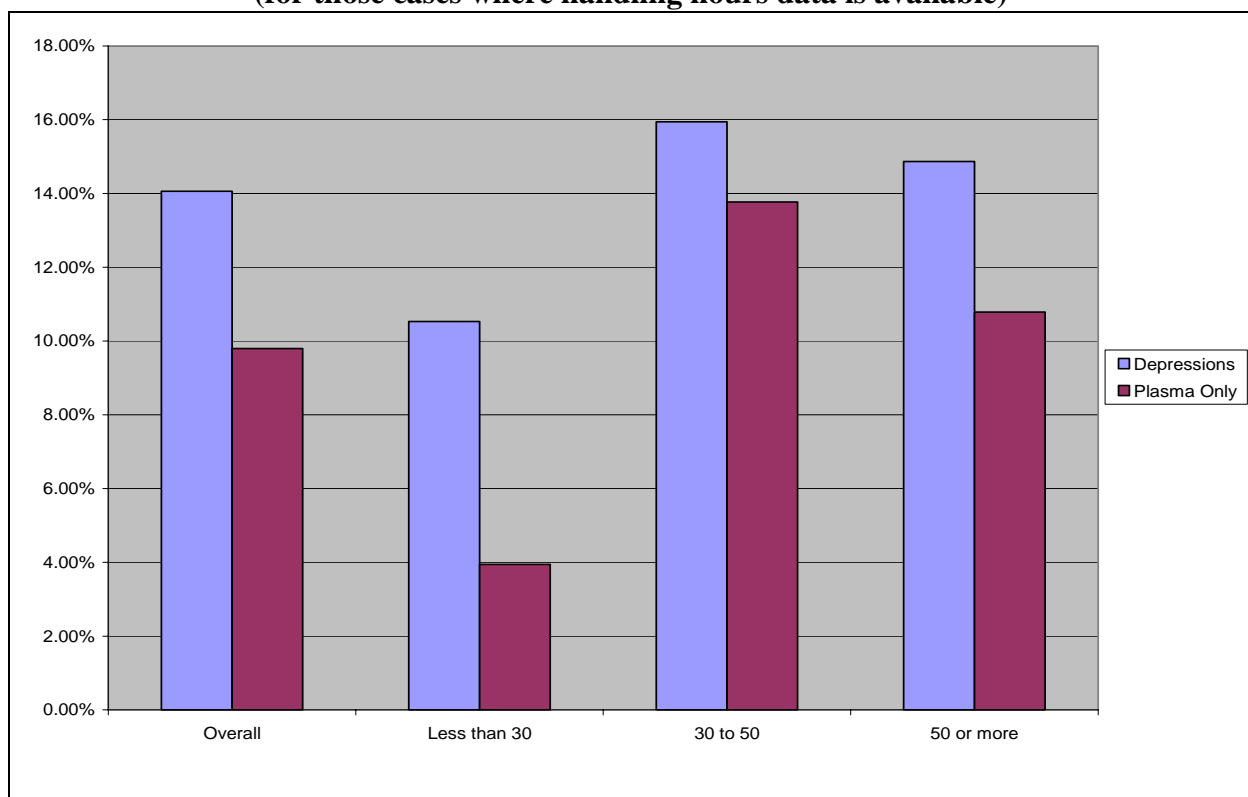
<sup>7</sup> In its December 2003 cost analysis, L&I used a 3 percent central estimate of the number of monitored employees who would experience depression, with a lower estimate of 1.2 percent and an upper estimate of 4.8 percent. The 2004 experience of 3.8 percent is well within the range of estimates previously identified and falls closer to the central estimate than to the upper. The December 2003 analysis did not estimate the number of employees who would experience a depression to the work practice investigation level.

<sup>8</sup> One of the areas of concern in treating this data as representative is illustrated by the fact that L&I has handling hours data on 77.3 percent of the work removal cases and 50.1 percent of the work practice investigation cases, compared to 69.5 percent of the tests overall. Another area of concern is that the rate of work practice investigation depression reported among those tests for which L&I has handling hours is 14.1 percent (by test, rather than by employee), compared to the 19.3 percent rate for the number of tests overall. The medical removal rate is 2.7 percent (again by test, rather than by employee), compared to the 2.4 percent rate for the number of tests overall. These may or may not be meaningful disparities, but they do suggest caution is necessary when drawing conclusions from this data.

### **Work Practice Investigations Correlated with Handling Hours**

In relation to the work practice evaluation requirement, the rate of such depressions among the monitored population for whom handling hours are available is 14.1 percent. As illustrated by Table 1, the rate for employees with greater than 50 reported hours in the previous 30 days is 14.9 percent, the rate for employees with between 30 and 50 hours is 15.9 percent, while the rate for employees with fewer than 30 reported hours is 10.5 percent. The table also includes separate results for plasma (serum) cholinesterase depressions, in relation to which the Scientific Team has suggested the laboratory data has a high reliability.<sup>9</sup>

**Table 1: Rate of Work Practice Investigation Depressions  
(for those cases where handling hours data is available)**



**Notes on Table 1:**

“Overall” reflects 89 total depressions and 62 plasma depressions of 633 periodic tests for which L&I has hours.

“Less than 30” reflects 16 total depressions and 6 plasma depressions of 152 periodic tests in that range.

“30 to 50” reflects 22 total depressions and 19 plasma depressions of 138 periodic tests in that range.

“50 or more” reflects 51 total depressions and 37 plasma depressions of 343 periodic tests in that range.

The number of depressions, when broken into categories by handling hours, is too small to draw conclusions with any level of statistical confidence (and it is probably not sufficiently representative to allow such conclusions in any case<sup>10</sup>). But the data does not contradict the

<sup>9</sup> Questions are periodically raised regarding the relationship between RBC and plasma depressions; it should be noted that it is to be expected that some employees would experience RBC depressions and other plasma depressions. Different pesticides have different effects on the two types of cholinesterase, and the degree to which the effects of exposure remain over time also vary.

<sup>10</sup> Even if 100 percent of the hourly handling reports had been received, the data still might not be representative for those employees with fewer than 50 hours of reported handling in the previous 30 days. Since the rule does not require periodic tests below that level, it is at least possible that employers who made the tests available at lower levels differ in some meaningful way from the population at large. For example, they may be more attentive to

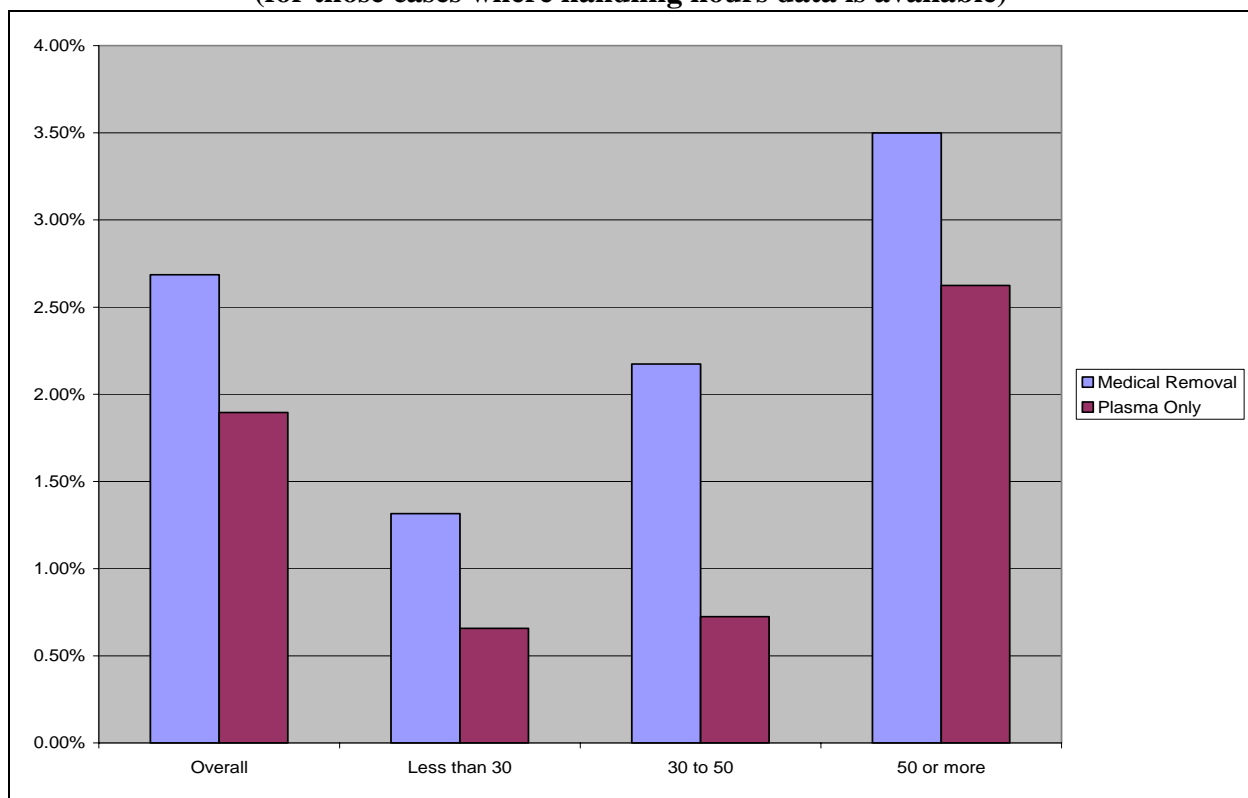
hypothesis that the risk of depression increases at higher exposure levels, and it tends to support the belief that there is a meaningful risk at lower levels, particular in the 30 to 50 hour range.

### **Medical Removals Correlated with Handling Hours**

Of the 22 employees with reported depressions to the work removal level, L&I has currently obtained handling hours on 17. Twelve of the 17 were reported to have handled covered pesticides at or above the 50-hour threshold. Three were reported to have handled covered pesticides between 30 and 50 hours, and two were reported to have handled pesticides fewer than thirty hours.

When compared to the monitored population for whom handling hours are available, the rate of medical removal (by test, rather than by employee) is 2.7 percent. As illustrated by Table 2, the rate for employees with greater than 50 reported hours in the previous 30 days is 3.5 percent, the rate for employees with between 30 and 50 hours is 2.2 percent, while the rate for employees with fewer than 30 reported hours is 1.3 percent.

**Table 2: Rate of Medical Removal Depressions  
(for those cases where handling hours data is available)**



#### **Notes on Table 2:**

“Overall” reflects 17 total removals and 12 plasma removals of 633 periodic tests for which L&I has hours.

”Less than 30” reflects 2 total removals and 1 plasma removal of 152 periodic tests in that range.

”30 to 50” reflects 3 total removals and 1 plasma removal of 138 periodic tests in that range.

”50 or more” reflects 12 total removals and 9 plasma removals of 343 periodic tests in that range.

health and safety concerns, making it *less* likely that a depression would be identified. Or they might be less attentive to administrative details (and therefore less aware of the monitoring thresholds), making it *more* likely that a depression would be identified. In addition, they are a much smaller sample of the employers they represent than are those employers who participated because their employees exceeded the 50-hour threshold.



The very small size of the numbers involved discourages conclusions about the risk represented by each category of handling hours. Once again, it is difficult to say more than that the data does not contradict the hypotheses that risk increases with higher exposure, and that it tends to support the conclusion that meaningful exposure exists at levels below those addressed by the 50-hour threshold.

## **Results of L&I Consultation Activity**

For each reported depression, L&I field staff contacted the affected employer and offered him or her a WISHA consultation pursuant to RCW 49.17.250. L&I, in discussions with the Stakeholder Advisory Committee, concluded that it was appropriate to use consultation resources, if possible, to follow up on such cases in a more cooperative manner rather than using the reports as the basis for an enforcement visit. Consultants were asked to gather basic information about the circumstances of the depression and the employer's response to it.

One of the inherent limitations of any such investigation is that it is likely to occur (at best) several weeks after the exposure in question has occurred and it is difficult to reconstruct events based on employer and employee interviews. This is a particular problem when the underlying issues may involve chronic exposures rather than a single event, or when work practices may be followed most of the time but not always. As a result, the consultations did not yield as much information as had been hoped, although they were suggestive in several respects.

Another limitation specific to the use of WISHA consultation resources to gather information is the confidentiality of the information obtained in such consultations, even if the employer and employee identities have been redacted. This confidentiality of the information obtained in consultation reports has been clarified by a recent Court of Appeals decision, and L&I is requesting waivers from the affected employers to allow more detailed data to be shared outside the department (L&I is making this request with the understanding that employer and employee identities will be protected even if the confidentiality of the consultation information is waived).

In many cases, employers with reported depressions appeared to have at least basic programs to protect their employees from pesticide exposure, and it was not always possible to document likely problems that may have contributed directly to the reported depression. However, several general recommendations can be shared based on the consultation information obtained to date (the following qualitative observations are primarily based on an initial document provided by the Region 5 WISHA consultation supervisor and confirmed by other L&I staff who have reviewed the consultation reports).

### **Respiratory Protection**

- Most handlers use half-face respirator masks. A half-face respirator leaves the skin above and around the respirator open to contamination. Mixers and applicators need to thoroughly wash their face, neck, and any other potentially exposed skin immediately after applications. Full-face respirators provide a higher level of protection than half-face respirators. The powered-air purifying type of respirator (helmet, hood, or full-face) provides a greater protective factor than a simple full-face respirator.
- Employers need to make sure that respirator cartridges and filters are changed for each shift or that a change-out schedule is documented and implemented to follow manufacturer specifications for the type of chemical used and the cartridge or filter.
- Fit testing of respirators needs to follow protocols identified in WISHA respirator rules.
- Employers need to ensure that respirators are stored in a clean and sanitary condition, away from sunlight and other potentially damaging environmental conditions. WISHA staff have seen effective storage consisting of sealed plastic containers, or large zip-lock type bags, and lockers, drawers, or shelves that protect the respirators from damage.
- Employees must be trained on every aspect of the employer's respiratory protection program.

### **Other Personal Protective Equipment (PPE)**

- Employers must enforce strict decontamination procedures every time handlers and applicators remove chemical gear such as coats, pants, gloves, boots, and respirators. This requires closer and stricter management of the employees since the applicators work on several blocks separated by several miles where management has not traditionally monitored work closely.
- Employers need to make sure pesticide-handling employees wash their gloves, coats, pants, and boots prior to removing any articles of PPE.
- Employers need to make sure pesticide-handling employees wash their hands after removing their gloves before eating, drinking, smoking, or using the restroom.
- Employers need to make sure all of their chemical gear fits the employees well.
- Employers need to select PPE based on the label for the pesticide.
- Daily inspection of all PPE must be performed to ensure that it is undamaged and functioning properly.
- Employers need to anticipate and address those “natural breaks” that may occur (such as an applicator’s return to the loading station), making sure that required cleaning supplies are available and that employees do not remove PPE without using these supplies.

### **Equipment and Maintenance**

- It is important that the tractors and sprayers are properly decontaminated between applications to ensure that employees are not exposed to pesticide residues. The tractors may have pesticides on the steering wheel, operation controls, seat, hood, and other areas. An employee who is performing maintenance like checking the oil levels of the tractor or simply moving the tractor to the loading area may not know that they’re working on a tractor that is contaminated with pesticides because the tractor was not properly decontaminated.
- Unclogging spray nozzles and cleaning spray equipment have been identified as potential sources for exposures in our fieldwork. Proper gloves (providing dexterity and protection) and other PPE must be worn when unclogging spray nozzles, so that employees do not contaminate themselves while performing this, and other, routine maintenance. Some farms have purchased pressure washers to decontaminate PPE, tractors, and implements.

One common factor in the operations with reported depressions was the application of covered pesticides using air-blast sprayers towed by tractors.

### **Headwear**

Some employees revealed that they wear a cotton baseball cap or bandana during application. Some mentioned that this helps keep the coat hood from falling onto the face during application. The cap can easily absorb and hold pesticides released during the air-blast application. The employee is not consistently washing the hat, thus providing a possible route for pesticide exposure. Employers need to address the headwear issue, possibly restricting its use during applications or providing chemical resistant visors or caps specifically for use during pesticide handling and application.

**Pesticide-Specific Observations**

- WISHA consultation staff encountered the suggestion that handlers may be less careful applying Sevin™ (a carbamate) when this is used as a chemical thinning agent, apparently believing it is not as dangerous as organophosphates because it is not being applied purely for insect control. Employers should stress in safety meetings and during chemical hazard communication training that all Sevin™ products, especially category I and II formulations, can cause cholinesterase depression and should be treated accordingly.
- WISHA consultation staff also noted that the current label on Lorsban 4E™ declares that it is a cholinesterase-inhibiting organophosphate, but it does not require respirator use.<sup>11</sup> It is still one of the pesticides requiring compliance with the cholinesterase rule. Our consultants indicated that, in each case, the farmers have gone beyond the label requirement and require the use of a respirator when applying Lorsban.™ Employee interviews confirmed this.

**Work Practice Investigations and Medical Removal**

- When a work practice investigation was indicated by a report of depression, several employers did little to investigate work practices prior to the WISHA consultation. It is not clear whether the employers presumed that the consultation itself would provide the necessary investigation of work practices. However, this investigation must occur as soon as practical; waiting for WISHA to perform the evaluation is not sufficient.
- WISHA consultants were able to confirm that, almost without exception, appropriate removal occurred as soon as the employer was notified of the depression (although in several cases there was an apparent delay in the employer receiving this notification from the medical provider).

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<sup>11</sup> L&I understands that the federal Environmental Protection Agency will be requiring respirator use on new labels as a result of the chlorpyrifos reregistration review.

## **The Scientific Advisory Committee (SAC)**

### **Committee Members**

The SAC, created in February of 2004, is chaired by Dave Kalman, PhD, who heads the University of Washington's Department of Environmental and Occupational Health Sciences. The remaining members of the committee include the following:

- Dave Bonauto, MD, Associate Medical Director of the Department of Labor and Industries, Safety and Health Assessment for Research and Prevention Program
- Rupali Das, MD, MPH, California Department of Health Services
- Allan Felsot, PhD, Washington State University Extension Specialist and Environmental Toxicologist
- Matthew C. Keifer, MD, MPH, Associate Professor of Environmental and Occupational Health Sciences, University of Washington
- Michael O'Malley, MD, MPH, Staff Physician with UC Davis Employee Health Services and consultant to the California Department of Pesticide Regulation's Worker Health and Safety Branch
- Steven Smith, MD, MPH, Contract Medical Director at Umatilla Chemical Disposal Facility, employed by Washington Defense Company, a subsidiary of Washington Group International, Inc.
- Juliet VanEenwyk, PhD, State Epidemiologist for Non-Infectious Conditions, Washington State Department of Health
- In addition, the SAC requested the addition, as consultants, of two members whose specialized expertise the SAC desired:
  - Barry Wilson, PhD, of the Department of Environmental Toxicology at the University of California, Davis
  - Gerald van Belle, PhD, Professor of Biostatistics and Environmental and Occupational Health Sciences, University of Washington

L&I appreciates the work of this group of volunteers and thanks their respective employers for making them available to assist in evaluating the rule and its implementation. John Furman, PhD, MN, CIC, Occupational Nurse Consultant with WISHA Policy & Technical Services, served as the primary staff support and liaison with L&I.

### **Draft Preliminary Report**

The SAC provided a draft report based on the available data from the first year's experience to L&I and to the Stakeholder Advisory Committee in November. The 70-plus page report contained a good deal of information and analysis, including a number of observations and recommendations for improvement directed to the Public Health Laboratory, medical providers and L&I. However, the stakeholder committee noted in its comments on the draft that the document was difficult to navigate and asked that the final document include an executive summary, as well as a single set of collected conclusions and recommendations. The SAC responded positively to these suggestions, as well as to other more specific comments, and is in the process of incorporating those comments so that an executive summary of the report can be made available by mid-January.

Although L&I had originally hoped that the report would be completed sooner, both L&I and the Stakeholder Advisory Committee encouraged the SAC to take the time necessary to produce a usable document, recognizing the high level of legislative and public interest in the issues. In addition, the delay does not prevent the lab or L&I from moving forward with those recommendations of most immediate interest since they have been kept aware of the SAC's work throughout the process.

One area of immediate interest is related to the question of whether the 30-hour threshold scheduled to take effect in February of 2005 should be modified. The SAC concluded as a group that there was not sufficient data available to make a recommendation on this issue. The handling threshold is discussed in more detail beginning on page 23 of this document.

## **The Stakeholder Advisory Committee**

### **Committee Members**

The Stakeholder Advisory Committee was created in January 2004. Its original members include the following:

- Jim Jesernig, Jesernig & Coyne, on behalf of the Washington Potato Growers (*grower representative*)
- Kirk Mayer, Washington Growers Clearinghouse (*grower representative*)
- Erik Nicholson, United Farmworkers (*farmworker representative*)
- Griselda Vega, Columbia Legal Services, on behalf of her clients (*farmworker representative*)
- Matthew Keifer, MD, MPH, University of Washington (*farmworker-designated scientific member*)
- Allan Felsot, PhD, Washington State University (*grower-designated scientific member*)
- Dorothy Tibbetts, Manager, Pesticides & Surveillance, DOH
- Ann Wick, Pesticide Program Manager, Washington State Department of Agriculture (WSDA)

Before the meeting on November 22, 2004, Mr. Jesernig temporarily withdrew from the committee and was replaced by Heather Hansen of the Washington Friends of Farms and Forests. Ms. Vega also has since notified L&I that she is leaving her current duties and can no longer serve on the committee. She will be replaced by Dan Ford, also of Columbia Legal Services.

Michael Wood, CSP, Senior Program Manager for L&I's WISHA Policy & Technical Services, facilitates the committee's meetings. Stefan Dobratz, CIH, L&I's Industrial Hygiene Program Manager, also participates (Mr. Dobratz's participation began while Mr. Wood was on temporary assignment to another part of the agency during the spring of 2004). In addition, the committee seated Nathan Lacy, PhD, Director of Environmental and Laboratory Services, DOH, and Dave Puente, Region 5 Compliance Manager, L&I, as advisory members.

### **Consensus Recommendations of the Stakeholder Advisory Committee**

At its November 22 meeting, the committee reached consensus on the following recommendations/observations for 2005. The following recommendations of the Stakeholder Advisory Committee to L&I reflect the position and opinion of that committee:

#### ***#1. Timely Follow-Up by L&I***

Both the labor and employer representatives have acknowledged the need for L&I to provide follow-up in a timely manner. The data gathered during L&I visits has become critical for a complete analysis by the Scientific Team. With the consultations taking up to a month to be opened, valuable data was lost. Employers and employees cannot be expected to reconstruct over two months of information. We strongly urge L&I to commit to perform follow-up visits within 72 hours of employer contact for workers who have depressions to the removal level and within two weeks for workers who have depressions to the alert level. L&I should confirm the removal of workers and the provision of medical removal benefits at the time of initial contact.

*#2. Timely Notification to both Employer and Employee regarding their Results*

It is imperative that, once L&I receives the results from CMDS, the agency provide the information to the medical provider and the employer, especially when removal of an employee is required. We recommend either same day turn around or within the next business day following L&I receipt of results. While not stated in the rule, L&I was notifying the employer by phone to assist in getting the information to the employer in advance of the lab mailing the results. We believe that this practice must continue in an effort to protect the health and safety of the handlers.

*#3. L&I Should Receive Employee Identities When a Depression Occurs*

In order for L&I to follow up with employers and employees, L&I staff who will make such contacts need to be given employee identities. If this cannot be done legally without a waiver from the employee, such a limited waiver allowing the employee's name to be shared with L&I should be obtained at the time the blood is drawn.

*#4. Employees Who Have Experienced Depression Should Be Interviewed*

L&I's on-site visits should include confidential interviews with any employees who have experienced a work removal or work evaluation depression. L&I should record how many employees who have experienced depressions to either the work practice investigation and work removal level were interviewed during the consultations.

*#5. A ChE Medical Monitoring Rule Should Continue Through 2005*

Although advisory committee members may disagree on the details of a rule and specific reasons to continue the program, the committee agrees that a cholinesterase-monitoring rule should continue through 2005.

*#6. More Data Needed*

There were significant gaps in the information necessary for a complete analysis of the implementation of the rule. We are all in agreement that there needs to be a more thorough compilation of data including, but not limited to, the following: handling hours for **every** employee that received a periodic test; time between notification of removal and actual removal; full name of pesticides used; description of engineering controls/closed systems/all PPE used; interviews of all employees with depressions to the alert or removal level; and interviews of a representative sample of employees who declined testing.

*#7. PNASH Participation*

L&I, in consultation with WSDA and DOH, should invite participation from the Pacific Northwest Agriculture Safety & Health center at the University of Washington to design a more detailed analysis of what work activities may or may not be associated with reported cholinesterase depressions.

*#8. Employer Reporting of Hours*

L&I and employer associations need to take steps to encourage compliance with the requirement to report pesticide handling hours for every employee given a periodic test.

*#9. Relationship with Medical Provider*

Medical providers should obtain occupational history as part of the pre-exposure medical history and evaluate alternate causes in the event a depression is reported.



The provider guidelines should specify that providers follow up with a handler after a depression to the alert or removal level. The guidelines must reflect the need for the provider to a) Notify employee as soon as is feasible, and no later than within 24 hours of receiving test results for a depression >20%; b) When an employee has a depression, the provider must notify the employee to come in for a follow-up test and further recommendations (including additional follow-up tests as appropriate). Provider guidelines should specify follow-up testing on a schedule consistent with the Scientific Advisory Committee's report (see page 6-7 of 11/12 draft). The health care provider responsibilities should include providing occupational health recommendations to employer.

**Recommendations for 2005 Handling Threshold**

The committee was not able to agree on one immediate issue – whether the 30-hour threshold in the rule should take effect as scheduled or the 50-hour threshold should remain in place throughout 2005. However, the committee did agree that the growers and farmworkers would present their recommendations on that issue separately to L&I allowing the department to consider whether to adjust the threshold before the start of the 2005 spray season. As agreed by the Stakeholder Advisory Committee, those separate recommendations (as well as a letter received from the Washington Growers League) accompany this report (see Attachments 2 through 5, which include the recommendations, as well as a discussion of other recommendations based on the 2004 experience).

The handling threshold is discussed in more detail beginning on page 23 of this document.

## **Overview of Quality Control Issues**

### **Quality Control Issues in General**

Laboratory quality control (QC) was one of the primary topics discussed by the Scientific Advisory Committee (SAC), particularly in their early meetings. Although formal publication of a Standard Operating Procedure by the Public Health Laboratory (PHL) was delayed, the SAC otherwise professed a relatively high level of overall confidence in the laboratory procedures and in the various QC measures being used to ensure reliable reporting. The present discussion will not attempt to address the various QC considerations in detail, leaving that to the more comprehensive and detailed SAC report (which is itself only an interim report in many respects, given the natural limitations of the data and the normal experiences of a “start-up” analytical program). However, several QC-related issues have received broader attention and are worthy of at least brief comment.

### **Amended Medical Removal Reports**

In July of 2003, the PHL re-evaluated several early baselines that had approached or exceeded laboratory normals, because DOH staff had noted that the affected handlers did not appear to be recovering after having been reportedly removed from pesticide handling duties. In doing so, the PHL concluded that the baselines in three cases had been overstated, causing an inaccurate report of employee depression (the corrected baseline also was relatively consistent with later testing of the same individuals). The PHL also identified a fourth case with a similar pattern, although there was no longer any of the sample available to allow for retesting.

DOH and L&I agreed to immediately rescind the previously issued alerts, allowing the affected employees to return to handling covered pesticides (based on the information provided by the employers, it appears that none of the four employees had actually missed work; rather, they all had been assigned alternate duties by their employers). L&I also asked the PHL to rerun the tests for the remaining 22 employees who had experienced reported depression to the medical removal level, and provide the results to the SAC for review and advice.

The SAC concluded that the earlier tests were probably more reliable and that there was insufficient information available to justify changing the previous results. It advised DOH and L&I not to adjust any further baselines (and criticized the agencies for having prematurely done so in the original four cases). It also recommended that the PHL conduct an analysis of the effect of extended storage on the analysis of red blood cell (RBC) cholinesterase levels. That analysis essentially concluded that RBC samples can be frozen and stored up to 4 weeks (as reflected in the adopted SOP) without interfering with the sample analysis, but that after 6 weeks samples can expect to yield a significantly lower RBC ChE level if they are reanalyzed.

L&I has chosen to disregard the four rescinded medical removal depressions for the purposes of this analysis (and therefore uses the figure 22, rather than 26, in discussions of the number of medical removals). However, L&I recognizes that the decision to rescind the alerts, while perhaps appropriate from a regulatory standpoint, may misrepresent the underlying data and its reliability. For this reason, L&I considers them to be “rescinded alerts and is not using them in its own statistical analysis,” but believes that their status is ambiguous and will therefore not describe them as “false positives” or “errors” unless and until the SAC chooses to do so.

### **Blind/Split Samples**

One particular QC method received broad attention, and that was the use of blind split samples<sup>12</sup> to test the laboratory's consistency in testing what would be expected to be identical samples. It should be noted that this was not the only QC protocol applied during 2004; however, the SAC recommended and L&I implemented a program to provide such samples. Although the program was implemented relatively late in the spray season (the tests were run in July, August and September), the information is still useful. Based on the recommendation of the SAC, L&I plans to run a similar program in 2005, throughout the spray season.

The 2004 split samples showed a high level of consistency in the laboratory's analysis of samples for plasma ChE. Of the 53 sets of split samples analyzed as part of this program, the highest variation noted was 5.4 percent. Only 2 of the 53 splits resulted in a variation greater than 5 percent, 12 resulted in a variation 2 percent or greater, and 25 resulted in a variation of 1 percent or greater. The average difference between the two samples in a split was 1.4 percent.

In comparing the plasma "baseline" sample results to sample results obtained during the "periodic" test, the likelihood of a reported depression of 20 percent or more was very low. There are 23 such sets of samples, providing 92 pairs of results (each combination of baseline and periodic samples provides four possible combinations). None of the 92 pairs represented a depression of more than 20 percent. The largest difference noted was a set of tests from a single individual. Of the four "pairs" that could have been reported for this individual, each resulted in an identified depression of between 16 and 17 percent. Of the 92 pairs, six (6.5 percent) showed a depression greater than 10 percent and 19 (2.1 percent) showed a depression greater than five percent.

The 2004 blind samples showed a lower level of consistency in the analysis of red-blood cell (RBC) cholinesterase samples. Of the 53 sets of split samples (30 "baselines" and 23 "periodic tests"), the highest variation was 29.7 percent, and three varied by 20 percent or more. Nine of the 53 resulted in a variation greater than 10 percent, and 19 resulted in a variation greater than 5 percent. The average difference between the two samples was 5.5 percent.

Even with this higher level of variation, the likelihood of a reported depression of 20 percent or more was relatively low. Again, there are 23 combinations of "baseline" and "periodic" samples, providing 92 pairs of results. Only one (1.1 percent) of those 92 pairs represented a depression of more than 20 percent. Three other pairs showed an increase of more than 20 percent. If the "baseline" and "periodic" samples are reversed (which might be appropriate, given the presumably unexposed nature of the individuals involved), the total number of possible combinations becomes 184. Of these 184 pairs, four (2.2 percent) represent a change of more than 20 percent, which would trigger the work practice investigation requirement in the rule.<sup>13</sup>

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<sup>12</sup> As used here, "blind split sample" refers to a process where the original sample is split and the two portions are submitted as though they were separate samples; the laboratory normally does not know they are handling QC samples, and in any case they are not able to identify which two samples would be expected to match one another.

<sup>13</sup> Some outside organizations have suggested that the L&I QC program demonstrated a high rate of depression (over 15 percent) to the work practice investigation level in individuals who were not exposed to pesticides. However, that is a misrepresentation of the data. It compares the most extreme values in each sample set, which increases the likelihood that an "error" will be made – it does not, however, adjust the calculation of the rate to reflect the fact that for each set of split baselines and split periodic tests, there are four possible combinations, rather than one. It also disregards the fact that in three of the four cases where the measured level changed more than 20 percent, the change was an increase, rather than a decrease. Finally, it does not acknowledge that the same analysis finds *no* variation that would trigger work practice investigation in the plasma ChE levels.

Of the four cases, two involved the same individual, whose blood draws for the periodic tests were difficult (this is the same individual and set of samples that resulted in the 29.7 percent variation between the splits). It is possible that this trauma caused problems in the samples for which the laboratory's 2004 method did not correct. However, based on a recommendation from the SAC, the PHL already plans to use a superior preparation method that would correct such errors. Also in response to an SAC recommendation, the PHL plans to be more rigorous in ensuring that samples improperly drawn or submitted to the laboratory by the provider are refused. The 2005 blind quality control program will be instructive in these regards.

Caution should be exercised in drawing broad conclusions from this data. As noted, it involved a relatively small time frame. In addition, it included only one mock set of "periodic" tests – presumably any error rate would be somewhat higher if the individual was subjected to a longer series of tests (the 2005 program will help to resolve this issue). And it does not substitute for the more sophisticated analysis of potential error rates that will be found in the SAC report and that will reflect the internal QC testing performed by the PHL. However, it does suggest that the analytical error rate, particularly in relation to plasma, is low.

## **Handling Hours Threshold for 2005**

Because of the structure of the rule and the need to communicate clear requirements about the 2005 spray season, L&I focused its present analysis on operational issues on the question of whether to allow the 30-hour threshold to take effect as planned. Other operational issues, such as those related to the balance between enforcement, consultation and research activities in gathering worksite-specific data, will be addressed in discussions with the Stakeholder Advisory Committee during January and February.

### **Status of Handling Hours Threshold in the Rule as Adopted**

The rule as adopted established a presumption that the handling hours threshold will drop to 30 hours in 2005 unless L&I acts to change it based on a conclusion that “the data collected during 2004 clearly demonstrates that the threshold should be either lower or higher than thirty hours.”<sup>14</sup>

Recommendations from members of the Stakeholder Advisory Committee, as well as a recommendation received from Michael Gempler of the Washington Growers League, accompany this report. In essence, the growers’ representatives argue that the threshold should remain at 50 hours, at least for another year. The farmworkers’ representatives argue that the handling threshold should go from 50 to 30 or even fewer hours.

### **Arguments in Support of 50-hour Threshold**

Advisory Committee member Kirk Mayer argues that the threshold should stay at 50 hours for the following reasons:<sup>15</sup>

- 1) the SAC did not find sufficient data to make a recommendation on the issue (and growers’ representatives – who could have encouraged growers to more fully comply with the law – did not know that the data was incomplete until reading the SAC’s draft report);
- 2) based on a comment by Dave Kalman, chair of the SAC, the design of the program was not appropriate to determining the relationship of hours to ChE levels, which is a failure on L&I’s part of take “the appropriate steps to ensure that such an analysis could be completed in a timely manner”;
- 3) the November 10 draft of the SAC report “documents that the Cholinesterase Medical Monitoring Program had problems at almost every level, from top to bottom,” and retaining the 50-hour handling threshold for 2005 will allow those issues to be addressed rather than “compounding the errors of 2004” with an increased number of samples.<sup>16</sup>

Advisory Committee member Heather Hansen argues that the threshold should stay at 50 hours for the following reasons:<sup>17</sup>

- 1) this is the first year “of a complex new program that is unique to Washington State” and with the lessons learned “we can go into 2005 with a clearer understanding of needs, expectations and functional procedures;

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<sup>14</sup> WAC 296-307-14810.

<sup>15</sup> This is only a summary of the basic argument presented by Mr. Mayer; see Attachment 2 for the e-mail on which this summary is based.

<sup>16</sup> In support of this argument, Mr. Mayer provided a list of 42 concerns and 11 recommendations that he gleaned from the draft SAC report

<sup>17</sup> This is only a summary of the basic argument presented by Ms. Hansen; see Attachment 3 for the e-mail on which this summary is based.

- 2) as the SAC draft report notes, “with the information available, no determination about the appropriate work hour threshold can be made,” which is partly the result of the lack of employer time records – and “the agricultural community was not made aware of this until after the scientific report came out”;
- 3) dropping the threshold will bring in new participants, including “a new group of growers who are not familiar with the program” and therefore “generate another year of uncertain data.”

Mike Gempler of the Washington Growers League also provided input specific to the 30-hour threshold, in which he recommended that the threshold remain 50 hours for 2005 for the following basic reasons:<sup>18</sup>

- 1) the decision to drop the threshold should be made based on an analysis of data, rather than the lack of data (and he was not able “to help improve the grower response” because he did not have information “that there was an insufficient response for an analysis”);
- 2) any decision should be delayed until L&I can work with growers and farmworkers “to collect a sufficient number of grower records in order to do a proper analysis and meet the spirit of the legislation and of the agreement between labor and the industry representatives that were involved in the negotiations,” noting that L&I also faces a perception issue (some members of his organization believe “that the lack of data, and the failure of design to develop a clear analysis was a ‘planned failure’ that would lead to an automatic decrease in the exposure threshold”).

#### **Arguments in Support of 30-hour (or Lower) Threshold**

Advisory Committee members Erik Nicholson and Griselda Vega argue that the 2005 threshold should be 30 hours, or even fewer, based on the following:<sup>19</sup>

- 1) the rule, and the prior agreement between worker and employer representatives, “requires that the coverage threshold for 2005 will be lowered to 30 hours in a 30-day period, unless the data collected during 2004 ‘clearly demonstrates that the threshold should be either lower or higher than 30 hours’”;
- 2) because “21% of the workers receiving periodic testing had depressions requiring a workplace investigation and 4.2% had depressions requiring removal” the threshold should be lowered;
- 3) the “preliminary data on handling hours” supports the 30-hour threshold because “the *average* handling hours in the 30 days prior to testing for workers who reached the alert or evaluation level was 46.3 – *less than* the 50-hour coverage threshold for 2004” and the average “for workers who met the *removal* level was 48.9 – again, less than the 50-hour threshold for 2004.”
- 4) because “at least one worker met the removal threshold with only 21 hours in the 30-day period prior to testing” a more thorough analysis should “determine whether the presumptive 30-hour threshold for 2005 is adequate.”

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<sup>18</sup> This is only a summary of the basic argument presented by Mr. Gempler; see Attachment 4 for the letter on which this summary is based.

<sup>19</sup> This is only a summary of the basic argument presented by Ms. Vega and Mr. Nicholson; see Attachment 4 for the letter on which this summary is based.

### **Other Factors**

Although suggested by the grower comments, one other factor should be considered explicitly – whether the PHL can handle the increased number of baselines if the 30-hour threshold goes into effect. The 2004 experience created an initial backlog when, during start-up, twice as many baselines as expected were submitted. The delays created by these backlogs created both operational and communication problems.

Based on information provided by the PHL, the laboratory (by running a second shift using the same equipment) can handle up to 750 samples (both plasma and RBC) per week. L&I's current estimate of the total number of baselines is 4,000, but some grower representatives suggested the possibility of as many as 6,000 to 8,000. If the peak month produces 6,000 baselines, those baselines could be run with minimal delays and within the 4-week time frame reflected by the PHL's current SOP; any backlog would be eliminated within six weeks. If more than 6,000 baselines are received within a single 30-day period, however, the lab would exceed its current analytical capacity. The current capacity also makes no provision for back-up.

### **L&I Discussion of Arguments in Favor of 50-hour Threshold**

Insufficient Data. It is true that not all employers have complied with the requirement to provide handling hours on employees receiving a periodic test. However, as discussed earlier in this analysis, handling hours on 69.5 percent of the periodic tests were available for this report, and some analysis of that data is both possible and now complete (see page 4 of this report).

Concerns about L&I's Communication Regarding Incomplete Responses. It is important that this issue be addressed if only, as Mr. Gempler notes, because of the potential perception that L&I did not make an effort to obtain these records. However, L&I took several direct actions to notify affected employers of the requirement and to ensure that the records were as complete as possible.

- On April 19, 2004, L&I sent letters to growers who had participating employees advising them of the passage of the requirement to report handling hours to L&I each month for each employee tested (the first monthly report would be due May 1, 2004);
- In June, L&I notified individual growers who had employees receive periodic tests but had not reported the required hours;
- In October, L&I again notified individual growers who had employees receive periodic tests but had not reported the required hours.

L&I staff also *did* share the lack of complete compliance with the Stakeholder Advisory Committee. It was discussed with the Stakeholder Advisory Committee several times prior to the receipt of the draft SAC report. Involved L&I staff believe it may have been mentioned as early as June (in the context of the second letter described above), although that is not reflected in minutes or other notes. However, the minutes do include the following references:

- As part of discussion of plans for selected enforcement activity, the August 2 meeting minutes include a passing reference to the issue, indicating that L&I “will look to see whether the growers are keeping records and whether they’re sending them in”;
- The September 24 meeting minutes state that L&I was “trying to match [consultation reports] with the growers’ report of hours if they’ve sent employees in for tests (and have provided the required report).” The minutes also state that L&I is “doing a follow-up mailing to request missing hours. About 50 percent of employers who had workers obtaining periodic tests have submitted hours.”

- An October 21 e-mail from Stefan Dobratz to various grower representatives notifies them of a pesticide application records request and provides a listing of the employers the request was sent to. The e-mail also tells them that L&I “will be mailing, in the near future, a letter to obtain missing handler hours reports from employers for cholinesterase tests. . . . The handling hours information is required to complete the data collection specified by the Legislature.” It further invites the recipients to call “if you have questions regarding either of the requests L&I is sending to agricultural employers.”

While it is possible to suggest that L&I should have assigned greater importance to the issue by raising it more emphatically during advisory committee meetings, it is difficult to suggest that L&I did not make an effort to obtain the records (stopping short, however, of using enforcement tools to do so). It is also true that the need to combine two separate databases (the analytical database, which also includes data that should not be part of the analysis and must therefore be excluded every time the databases are combined, and the handling hours database) makes those data matches cumbersome and difficult to update quickly. However, that task has now been completed and the discussion earlier in this document reflects an analysis of the currently available data.

Concerns About the Design of the Program as It Relates to the Handling Hours Threshold. In discussing the lack of a recommendation regarding the handling hours threshold in the SAC draft report with the Stakeholder Advisory Committee, SAC Chair Dave Kalman made the observation that the “program is not designed” to answer the question about what the threshold should be. This comment, the source of Mr. Mayer’s concerns about L&I’s failure to appropriately design the program, referred specifically to the fact that a program with a monitoring threshold of 50 hours could not reasonably be expected to provide sufficient data to assess the exposure relationships *under* 50 hours.<sup>20</sup> In response to a request to clarify his comments after Mr. Mayer’s e-mail, Dr. Kalman sent the following e-mail to members of the Stakeholder Advisory Committee:

As requested, I am restating my comment regarding the basis for 30 / 50 hour requirements. The primary objective of the monitoring program is not to test the question “what is the relationship between hours of pesticide work reported by employers and the likelihood of ChE depression?”. To design a study to address this question, one would like a range of reported pesticide handling hours worked, deliberately including either control groups or groups with few pesticide handling hours, in order to see how large changes in hours relates to changes in ChE. This amounts to deliberately including workers for whom the expectation is little likelihood of overexposure, and is at odds with the intent of the ChE monitoring program which aims to focus on those workers having the greatest potential risk. This means that, independent of how completely employers complied with reporting requirements, there is no guarantee that Year 1 data would shed much light on this question. (Of course, some employers did report hours for workers with fewer than 50. IF that sub group is a representative sample of all workers/employers, then those data could be used).

That is the basis for my “program design” comment. The committee as a group has agreed that we lack sufficient data to make a judgment about 30/50 hours but did not discuss or adopt my statement.

It is unfortunate that expectations varied so significantly about the likelihood that the data would be available to draw firm or statistically significant conclusions. However, it seems likely that the data to draw such conclusions will not be available as long as the reporting threshold remains at 50 hours, in spite of the occasional participation by employers who are not required to do so

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<sup>20</sup> Dr. Michael Silverstein, Assistant Director for WISHA Services, testified about this potential problem in the legislative hearings that subsequently resulted in the adoption of the requirement for growers to report handling hours. L&I recognized, and publicly acknowledged at the outset, that the ability to draw meaningful conclusions from the handling hours data was likely to be limited. See Footnote 8 above.



(even if such a group were large enough, the likelihood that it would be a truly representative sample is quite low).

Concerns that the “Start-Up” Problems of the First Year Will Be Repeated if the Threshold Changes. It is probably true that the program would operate more smoothly if the threshold were left at 50 hours during 2005. But those concerns must be balanced against the presumption in the rule that the threshold would be lowered, the real risks faced by affected workers who would not be protected, and by the need for additional data (which is better served by lowering the threshold than by leaving it at 50 hours). None of the issues identified in the various recommendations and critiques of the program, by the SAC and by the Stakeholder Advisory Committee members individually and as a group, directly suggest that moving to the 30-hour threshold as planned would present an operational problem, with the possible exception of laboratory capacity.

In relation to the PHL’s analytical capacity, L&I’s best estimates suggest that the existing capacity is likely to be able to handle the workload. In any case, L&I has agreed to the purchase of a second piece of analytical equipment in order to provide the back-up capacity recommended by the SAC (and particularly important in assessing the time-sensitive periodic samples). That back-up capacity also offers the potential to effectively double the laboratory capacity if needed, making it possible to complete the necessary baselines within operating standards even if the high estimate of 8,000 baselines turns out to be accurate.

#### **L&I Discussion of Arguments in Favor of 30-hour (or Lower) Threshold**

The Presumption Created by the Rule. Advocates for a lower threshold correctly note that the rule establishes a presumed threshold by adopting the 30-hour threshold, effective February 1, 2005, unless data justifies making a change. It should be noted that this argument applies only to the suggestion that the 30-hour threshold be implemented, not that a lower threshold be considered and perhaps adopted. It is also important that this decision be made only in the context of the legislatively-required analysis of the available data, particularly the correlation of handling hours to the degree such correlation is possible.

The Levels of Identified Depressions Justify a Reduction in the Threshold. This appears to suggest that even in the absence of data showing a risk at lower levels, the documented risk at higher levels would be sufficient to reduce the threshold. This argument may not be persuasive, but it is also not critical given that the available data does show a risk at lower levels, although it does not allow it to be readily quantified.

The Handling Hours Data Supports the 30-Hour Threshold. More significant than the averages that were available in the preliminary analysis, the data regarding the depressions identified (both at the work practice investigation and medical removal levels) among employees with fewer than 50 handling hours suggests that there is a risk at lower levels.

Suggestion that the Handling Hours Data May Support an Even Lower Threshold. The data available to L&I indicates that two employees met the removal threshold with fewer than 30 hours handling covered pesticides during the previous 30 days. However, the data is insufficient from which to draw conclusions about the risk at such levels.<sup>21</sup> Ultimately, the recommendation

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<sup>21</sup> Not only are the numbers very small, it is possible that there may be confounding variables. When discussions of one or two cases are involved, the chance of alternate causation becomes more significant. In addition, the possibility that the employer’s report of handling hours may not have been entirely accurate must be considered; while there is no indication of a widespread problem, there are indications of limited problems and it is possible that those problems may leave a false impression in this case.

here is to analyze the data closely to draw appropriate conclusions – that analysis, however, will require additional data.

**L&I's Decision Related to the 30-hour Threshold**

L&I has concluded that the need to comply with the expectations of the rule as adopted, to continue to provide effective protections to workers during 2005 based on the best currently available evidence, and to ensure that more complete data for future analyses all support implementing the 30-hour threshold as scheduled. However, L&I also believes that the question of the appropriate monitoring threshold has not been resolved, and that it should be revisited next year as additional data accumulates.